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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,088	01/21/2000	Sung-Yun Kwon	7010-0014	5348

7590 03/22/2004

Alisa A Harbin
Chiron Corporation
4560 Horton Street M/S R-338
Emeryville, CA 94608-2916

EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/489,088	KWON ET AL.
Examiner	**Art Unit**
Isis Ghali	1615

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-40* is/are pending in the application.

4a) Of the above claim(s) *33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 12/15/2003.

Claims 1-18, and 20-40 are pending. Claims 1-18, and 20-32 are included in the prosecution. Claims 33-40 are withdrawn from further consideration as being drawn to a nonelected Group II.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-18, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/29134 ('134) in view of US 5,630,796 ('796).

Claim 1 reads as a method for administering a therapeutic agent to the skin or mucosa comprising accelerating particles into or across the skin or mucosa using a needless syringe; and topically positioning a transdermal drug delivery device or occlusive dressing on the area of the skin or mucosa.

WO '134 teaches a method of enhancing the permeability of a permeant (active agent) across of a biological membrane including skin or mucosa utilizing microporation of the membrane at the site of administration, followed by contacting the porated surface by the active agent and a permeation enhancer (abstract; page 9, lines 5-10; page 10, line 8; page 15, line 14; page 19, lines 6-15; page 34, lines 5-9; page 100, lines 14-16). The active agent includes polypeptide and vaccine associated with a carrier such as microcapsules or microparticles (page 14, lines 19-25; page 15, lines 1-4; page 29, line 11). The micropores should not be smaller than 1 micron in diameter (page 25, lines 3-4). The pores can be covered by transdermal patch to deliver the active agent through the skin (page 118, Example 50). The reference suggests forming the pores using any non-invasive means that do not require entry of needle to the skin or mucosa or invasive instruments (page 32, lines 10-11).

WO '134, however, does not teach the needleless syringe used to form the skin pores, but suggests forming the pores using any non-invasive means that do not require entry of needle to the skin or mucosa or invasive instruments.

US '796 teaches a noninvasive method comprising needleless syringe for effective transdermal delivery of particles containing a therapeutic agent. The needleless method provides safe quick method with less pain and no risk of infection. The active agents include viruses or proteins (antigen), insulin with a carrier (adjuvant) or a placebo. Injection velocities may be between 200 up to 3000 m/sec. and the particle size ranges from 0.1 to 250 micrometer. The particles can be made from metal. The drug particles can be encapsulated. More than one therapeutic agent can be injected together. See the abstract, col.1, lines 61-63; col.2, lines 30-37; col.4, lines 1-23, 40-55; col.8, lines 17-20; col.10, example 2.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a method for administering a therapeutic agent to the skin or mucosa comprising forming pores in the skin or mucosa using noninvasive means followed by topical application of the active agent by a patch as disclosed by WO '134, and use the noninvasive needleless syringe disclosed by US '796 to form the skin pores, motivated by the teaching of US '796 that the needleless method is safe quick method with less pain and no risk of infection, with reasonable expectation of having a method for delivery of active agents across the skin or mucosa comprising porating the skin with needleless syringe followed by application of a topical

device such a method accelerates the drug delivery through the skin or mucosa to the systemic circulation safely and quickly with no pain.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

ISIS GHALI
PATENT EXAMINER